

B. Kristian W. Rasmussen, III, FL Bar No. 0229430
LEVIN, PAPANTONIO, THOMAS,
MITCHELL, ECHSNER & PROCTOR, P.A.
316 South Baylen Street, Suite 600 (32502)
P. O. Box 12308
Pensacola, Florida 32591
Telephone: (850) 435-7023
Facsimile: (850) 435-7020

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
(SAN FRANCISCO DIVISION)

In re: Bextra and Celebrex Marketing Sales
Practices and Product Liability Litigation

MDL No. 1699

District Judge: Charles R. Breyer
Magistrate:

WILLIAM POTEATE, individually,
Plaintiff,

v.

PFIZER, INC., PHARMACIA CORP., and
G.D. SEARLE & CO.,

Defendants.

Case No. _____

CIVIL COMPLAINT

JURY TRIAL DEMANDED

WILLIAM POTEATE, Plaintiff, through counsel and pursuant to applicable law, brings this action against Defendants PFIZER, INC., PHARMACIA CORP., and G.D. SEARLE & CO. (hereafter "Defendants") and alleges as follows:

I. PARTIES

1. This is an action for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe medication Valdecoxib, trade name BEXTRA® ("Bextra").

2. Plaintiff was at all relevant times an adult resident citizen of the State of North Carolina, residing at 5329 Highway 67, Booneville, NC 27011.

3. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York, New York. In 2003, Pfizer acquired Pharmacia for nearly \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling the drug Valdecoxib, under the trade name Bextra in North Carolina and nationwide.

4. Defendant Searle ("Searle") is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Bextra nationwide and in North Carolina. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged within this Complaint.

5. Defendant Pharmacia ("Pharmacia") is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling Bextra nationwide and in North Carolina.

II. JURISDICTION AND VENUE

6. This is an action for damages, which exceeds seventy-five thousand dollars (\$75,000.00).

7. There is complete diversity of citizenship between the Plaintiff and Defendants. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there is complete diversity of citizenship between Plaintiff and Defendants.

8. This action is being filed in the Northern District of California Pursuant to MDL 1699, Pretrial Order No. 2. However, venue is proper in the Middle District of North

1 Carolina ("the District") pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and
2 distributed the dangerous product in the district, thereby receiving substantial financial benefit
3 and profits the dangerous product in the district, and reside in the district under 28 U.S.C.A.
4 § 1391(c), such that venue is proper.

5 9. At all relevant times herein, Defendants were in the business of designing,
6 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and
7 selling their product, Bextra. Defendants at all times relevant hereto designed, developed,
8 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce
9 (including North Carolina) the aforementioned prescription drug. Defendants do substantial
10 business in the State of North Carolina, advertise in the district, receive substantial compensation
11 and profits from sales of Bextra in the District, and made material omissions and
12 misrepresentations and breaches of warranties in the District so as to subject them to *in personam*
13 jurisdiction in the District. In engaging in the conduct alleged herein each defendant acted as the
14 agent for each of the other defendants, or those defendant's predecessors in interest.

15 **III. INTERDISTRICT ASSIGNMENT**

16 10. Assignment to the San Francisco Division is proper as this action is related
17 to *In Re: Bextra and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to
18 the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6,
19 2005.

20 **IV. FACTUAL BACKGROUND**

21 **A. Facts Regarding Plaintiff**

22 11. Plaintiff was prescribed, and began taking, Bextra on or about January 15,
23 2004.

24 12. As a direct and proximate result of using Bextra, Plaintiff suffered severe
25 cardiovascular injuries. Specifically, on or about December 20, 2004, Plaintiff suffered a
26 myocardial infarction ("heart attack") which caused Plaintiff's damages and injuries set forth
27 herein.
28

1 13. Unaware of the risks presented by Bextra, or that Bextra was the cause of
2 his injuries, Plaintiff continued to take Bextra until February 2, 2005.

3 14. Plaintiff and Plaintiff's healthcare providers were at the time of Plaintiff's
4 adverse cardiovascular event unaware—and could not have reasonably known or have learned
5 through reasonable diligence—that such injury directly resulted from Defendants' negligence and
6 otherwise culpable acts, omissions, and misrepresentations or from Plaintiff's ingestion of Bextra.

7 15. Plaintiff used Bextra in a proper and reasonably foreseeable manner and
8 used it in a condition that was substantially the same as the condition in which it was
9 manufactured and sold.

10 16. Plaintiff would not have used Bextra had Defendants properly disclosed the
11 risks associated with the drug.

12 **B. Facts Regarding Bextra**

13 17. Bextra is one of a class of pain medications called non-steroidal anti-
14 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade
15 name Advil) are examples of well-known NSAIDs.

16 18. NSAIDs reduce pain by blocking the body's production of pain
17 transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX
18 enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and
19 COX-2 enzymes.

20 19. In addition to decreasing inflammation, the prostaglandins that are
21 supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the
22 stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the
23 medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric
24 tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including
25 stomach ulceration and bleeding. Prostaglandin I2 is the predominant cyclooxygenase product in
26 endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation,
27 and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit
28 Thromboxane A2 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected.

1 Thromboxane A₂ is a potent platelet aggregator and vasoconstrictor which is synthesized by
2 platelets. Therefore, while the older NSAIDs suppress platelet aggregation and vasoconstriction,
3 the COX-2 inhibitors support it. Traditional NSAIDs like aspirin reduce pain/inflammation and
4 therefore pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be
5 expected, traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do
6 not cause blood clots, rather they actually reduce the risk of clots and help protect heart function.

7 20. Defendants and other pharmaceutical companies set out to remedy these
8 ulcer and bleeding problems suffered by some NSAID users by developing “selective” inhibitors
9 that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of
10 gastric tissue while still reducing inflammation.

11 21. In making this decision, Defendants and their predecessors in interest either
12 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2
13 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood
14 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,
15 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

16 22. The defendants launched Celebrex, the first of the three major COX-2
17 inhibitor drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and
18 consumers of the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In
19 May 1999, Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

20 23. Seeking increased market share in this extremely lucrative market,
21 Defendants, and their predecessors in interest, also sought approval of a “second generation”
22 selective COX-2 inhibitor and filed for FDA approval of Bextra on January 16, 2001 for the
23 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief
24 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

25 24. The FDA granted approval of the new drug on November 16, 2001, for two
26 particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms
27 of osteoarthritis and rheumatoid arthritis.
28

1 25. The FDA did not grant approval to market and promote Bextra for the
2 management or prevention of acute pain.

3 26. The FDA did not grant approval to promote Bextra as more effective than
4 other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers
5 or gastric bleeding.

6 27. Even without a label that allowed Defendants to legitimately claim superior
7 safety, when Defendants, and their predecessors-in-interest, began marketing Bextra in early
8 2002, Defendants and their representatives and agents misrepresented the safety profile of Bextra
9 to consumers, the medical community, healthcare providers, and third party payors. Defendants
10 proceeded to promote, market, sell, and distribute Bextra as a much safer and more effective pain
11 reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

12 **C. Facts Regarding Bextra's Safety**

13 28. The potential for cardiovascular risk of selective COX-2 inhibitors was
14 known to Defendants long before the FDA granted market approval for Bextra. By 1997, and
15 prior to the submission of the New Drug Application (the "NDA") for Bextra, Defendants were
16 aware that, by inhibiting COX-2, Bextra altered the homeostatic balance between prostacyclin
17 synthesis and thromboxane and thereby, increased the prothrombotic effects of the drugs, causing
18 blood clots to form in those who ingested it. *See Topol, E.J., et al., Risk of Cardiovascular*
19 *Events Associated with Selective Cox-2 Inhibitors, JAMA, August 22, 2001 at 954.* Although all
20 COX-2 inhibitors have this mechanism of action, Bextra was the most selective COX-2 inhibitor
21 proposed for approval. Accordingly, it had the greatest potential to cause adverse cardiovascular
22 and cerebrovascular events.

23 29. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of
24 Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on
25 October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as
26 Bextra, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet
27 aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.
28

1 30. Nevertheless, the Defendants submitted an NDA to the FDA for Bextra,
2 omitting information about the extent of the risks associated with Bextra. Without a complete
3 picture of the potential hazards associated with the drug, the FDA approved Bextra on or about
4 November 16, 2001.

5 31. Based on the studies performed on Bextra, other COX-2 inhibitors, and
6 basic research on this type of selective inhibitor which had been widely conducted, Defendants
7 knew when Bextra was being developed and tested that selective COX-2 inhibitors posed serious
8 cardiovascular risks for anyone who took them, and presented a specific additional threat to
9 anyone with existing heart disease or cardiovascular risk factors.

10 32. Studies show that selective COX-2 inhibitors, including Bextra, decrease
11 blood levels of a prostacyclin. When those levels fall, the arteries are more vulnerable to clotting,
12 high blood pressure, heart attack, and stroke.

13 33. The defendants marketed Bextra in the United States for three years (April,
14 2002 – April 7, 2004). During that time the FDA forced the defendants to strengthen the warning
15 label several times. The enhanced warnings followed in the wake of the results of additional
16 cardiovascular studies performed by Defendants, as well as numerous complaints to the FDA
17 regarding various adverse events.

18 34. Prior to strengthening the warning for Bextra, Defendants had knowledge
19 of the coronary and cardiovascular safety risks of Bextra from several studies. *See e.g., Otto,*
20 *E.O., Efficacy and Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in*
21 *Patients Undergoing Coronary Artery Bypass Surgery, The Journal of Thoracic and*
22 *Cardiovascular Surgery*, June 2003 at 1481.

23 35. Even Defendants' own (and Pfizer funded) post- drug approval meta-
24 analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data
25 showing an increased cardiovascular risk in patients treated with Bextra after undergoing
26 coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood
27 clots in the legs and lungs. The results were particularly relevant and striking as each of the study
28

1 participants who was a post-bypass surgery patient was taking anti-clotting agents at the time
2 their exposure to Bextra was being tracked.

3 36. In mid-January 2005, a peer-reviewed paper from the University of
4 Pennsylvania found that in patients having heart bypass surgery, those who took Bextra in the
5 intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a
6 heart attack or stroke.

7 37. Despite years of studies on selective COX-2 inhibitors, as well as the
8 disturbing new studies specifically analyzing the risks of Bextra, Defendants failed to take any
9 action to protect the health and welfare of patients, but instead, continued to promote the drug for
10 sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis
11 Drug Advisory Committee meetings.

12 38. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily
13 withdraw" Bextra from the U.S. market, stating:

14 . . . the Agency has concluded that the overall risk versus benefit
15 profile of Bextra is unfavorable. This conclusion is based on the
16 potential increased risk for serious cardiovascular (CV) adverse
17 events, which appears to be a class effect of non-steroidal anti-
18 inflammatory drugs (NSAIDs) (excluding aspirin) . . . and the fact
19 that Bextra has not been shown to offer any unique advantage over
20 the other available NSAIDs. (FDA Alert for Healthcare
21 Professionals, April 7, 2005.)

22 39. Continuing, the FDA noted:

23 Bextra has been demonstrated to be associated with an increased
24 risk of serious adverse CV events in two short-term trials in patients
25 immediately post-operative from coronary artery bypass graft
26 (CABG) surgery FDA has concluded that it is reasonable to
27 extrapolate the adverse CV risk information for Bextra from the
28 short-term CABG trials to chronic use given the fact that other
COX-2 selective NSAIDs have been shown in long-term controlled
clinical trials to be associated with an increased risk of serious
adverse CV events (e.g., death, MI, stroke), and the well described
risk of serious, and often life-threatening gastrointestinal
bleeding To date, there have been no studies that demonstrate
an advantage of Bextra over other NSAIDs that might offset the
concern about the serious skin risks, such as studies that show a GI
safety benefit, better efficacy compared to other products, or
efficacy in a setting of patients who are refractory to treatment with
other products."

40. Dr. Garret A. Fitzgerald, cardiologist and pharmacologist at the University

1 of Pennsylvania, presented the preliminary results of his Bextra study at the American Heart
2 Association meeting in New Orleans, Louisiana. His study, containing 12 trials including 5,930
3 patients, found 2.19 times the number of strokes among patients given Bextra. *New York Times*,
4 Nov. 10, 2004.

5 41. Instead of studying Bextra prior to its market launch, the Defendants
6 simply relied upon data and information gathered from Celebrex trials and studies. The Celebrex
7 data put Pfizer on notice that Cox-2 NSAIDs are, at the very least, associated with a
8 disproportionately increased number of adverse cardiovascular events. Taking the results from
9 the Celebrex trials in conjunction with the available medical literature; the Defendants knew
10 about the increased incidence and association between Bextra and the potentially life-threatening
11 dangers it could cause.

12 42. The New York Times uncovered the truth about the inadequate studies by
13 interviewing Pfizer researcher Dr. Feczko - Pfizer's president for worldwide development.

14 Over all, Pfizer has performed much less research on Bextra than
15 on Celebrex, Dr. Feczko said. Most of the company's studies of
16 Bextra have been short term, with many lasting only two weeks.
17 As a result, Pfizer has less data to support its contention that Bextra
18 is safe, he said.

19 ***

20 Dr. Feczko of Pfizer explained that the company felt it was not as
21 important to study Bextra extensively because the company
22 believed that the drug was similar to Celebrex.

23 *The New York Times*, February 5, 2005.

24 43. The Celebrex data relied upon by the Defendants was not adequate. On
25 July 23, 2005, the New England Journal of Medicine published the results of its investigative
26 research noting: "Most data on the cardiovascular risks associated with celecoxib have come
27 from observational studies or short-term randomized trials." N. ENG. J. MED. 352;25 at 2649.

28 44. On December 23, 2004, three (3) researchers from the well-respected
Vanderbilt University published an article in the New England Journal of Medicine. The doctors
wrote: "To protect the safety of the public, we write to recommend that clinicians stop prescribing

1 Valdecoxib (Bextra) except in extraordinary circumstances.” N. ENG. J. MED. 351;26. The
2 authors cite to two (2) recent studies “which showed a 3-fold increase in serious cardiovascular
3 injuries in patients receiving Valdecoxib after coronary-artery bypass grafting.” Later, on
4 February 17, 2005, the New England Journal of Medicine published the results of a study
5 conducted by eight (8) doctors with similarly alarming results. N. ENG. J. MED. 2005;352.

6 45. In January 2005, Drs. Fitzgerald, Furberg and Psaty published an editorial
7 in *Circulation*, the official journal of the American Heart Association. This editorial was based
8 on a meta-analysis of two (2) clinical studies, and discusses the association between intravenous
9 administration of an identical drug, and oral administration of Bextra. All three doctors found a
10 “3-fold higher risk of cardiovascular injuries with the drug than with a placebo.” *Cir.* 2005;
11 111:249.

12 46. The scientific data available during and after Bextra’s approval process
13 made clear to Defendants that their formulation of Bextra would cause a higher risk of blood
14 clots, stroke and/or myocardial infarctions among Bextra consumers, alerting them to the need to
15 do additional and adequate safety studies.

16 47. As stated by Dr. Topol on October 21, 2004, in *The New England Journal*
17 *of Medicine*, outlining Defendants’ failure to have conducted the necessary trials before
18 marketing to humans “. . . it is mandatory to conduct a trial specifically assessing cardiovascular
19 risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with
20 established coronary artery disease, who frequently have coexisting osteoarthritis requiring
21 medication and have the highest risk of further cardiovascular events.”

22 48. Dr. Topol was also the author on the study published in August 2001 in
23 JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in
24 persons who used COX-2 inhibitors.

25 49. Based upon readily available scientific data, Defendants knew, or should
26 have known, that their pre-approval testing of Bextra did not adequately represent the cross-
27 section of individuals who were intended consumers and therefore, likely to take Bextra.
28 Therefore, Defendants’ testing and studies were grossly inadequate. *See, e.g.*, PDR entry for

1 Bextra (noting that: "Platelets: In four clinical studies with young and elderly (≥ 65 years)
2 subjects, single and multiple doses up to 7 day mg BID had not effect on platelet aggregation").

3 50. Had Defendants done adequate testing prior to approval and "market
4 launch," rather than the extremely short duration studies done on the small size patient base that
5 was actually done) Pharmacia and Searle's scientific data would have revealed significant
6 increases in incidence of strokes and myocardial infarctions among the intended and targeted
7 population of Bextra consumers. Adequate testing would have shown that Bextra possessed
8 serious side effects. Defendants should have taken appropriate measures to ensure that their
9 defectively designed product would not be placed in the stream of commerce and/or should have
10 provided full and proper warnings accurately and fully reflecting the scope and severity of
11 symptoms of those side effects should have been made.

12 51. In fact, post-market approval data did reveal increased risks of clotting,
13 stroke and myocardial infarction, but Defendants intentionally suppressed this information in
14 order for them to gain significant profits from continued Bextra sales.

15 52. Defendants' failure to conduct adequate testing and/or additional testing
16 prior to "market launch" was based upon their desire to generate maximum financial gains for
17 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2
18 inhibitor market. At the time Defendants manufactured, advertising, and distributed Bextra to
19 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding
20 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants
21 knew that if such increased risks were disclosed, consumers would not purchase Bextra, but
22 instead would purchase other cheaper and safer NSAIDs.

23 **D. Facts Regarding Defendants' Marketing and Sale of Bextra**

24 53. The defendants rushed Bextra to the market in an effort to regain Cox-2
25 market share. In response to the introduction of Vioxx, and without performing adequate
26 research, the Defendants hastily introduced their own more selective Cox-2 inhibitor, Bextra, to
27 the market. In doing so, Pfizer, admittedly, relied upon problematic research results from its
28 study of Celebrex.

1 54. Pfizer stuck to its original plan – focus on marketing and avoid studying
2 Bextra. Thus, it was reported: “The positioning for Bextra began more than a year and a half
3 before it hit the market. Pharmacia conducted research about the arthritis market to examine gaps
4 in treatment, said Sylvia McBrinn, Pharmacia’s Vice President for global marketing for Bextra.”¹
5 Bextra’s marketing research was conducted over a year and a half, while science took a backseat,
6 with one small study for Bextra lasting not even one year and the rest lasting only weeks in
7 duration.

8 55. At all times relevant herein, Defendants engaged in a marketing campaign
9 with the intent that consumers would perceive Bextra as a safer and better drug than its other
10 NSAIDs and, therefore, purchase Bextra.

11 56. Such an ineffective and unreasonably dangerous drug could only be widely
12 prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the
13 Defendants’ marketing campaign was fraudulent and misleading. But for fraudulent and
14 misleading advertising, consumers would not have purchased Bextra, a more costly prescriptive
15 drug, that was not effective for its intended purposes.

16 57. On January 10, 2005 the FDA issued Pfizer a written reprimand for its
17 promotional activities. The reprimand reads: “These five promotional pieces [3 Celebrex and 2
18 Bextra] variously: omit material facts ... and make misleading safety, unsubstantiated superiority,
19 and unsubstantiated effectiveness claims.” This was not the Defendants first offense related to its
20 Cox-2 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting: “DDMAC has
21 reviewed these promotional pieces and has determined that they are false or misleading because
22 they contain unsubstantiated comparative claims, misrepresentations of Celebrex’s safety profile,
23 and are lacking in fair balance.”

24 58. Bextra was never approved for the treatment of acute pain. Without such
25 approval, Pfizer was prohibited from marketing Bextra for such an indication. Nevertheless, in
26 May of 2002, Pfizer issued a press release announcing the publication of a study in the Journal of
27 the American Dental Ass’n (JADA) concluding that Bextra is effective in the treatment of acute

28 ¹ *New Jersey Record*, North Jersey Media Group, Inc., April 14, 2002.

1 pain associated with dental surgery. Interestingly, the dental study was sponsored by the
2 defendants and three of the five authors were employees of Pharmacia.

3 59. Essentially, Pfizer was attempting to circumvent the FDA by promoting a
4 study it funded and authored for an unapproved use. Once the results were published, Pfizer's
5 aggressive promotional campaign continued. Pfizer issued a press release touting Bextra's
6 efficacy for the treatment of acute pain. After the press release, Dr. Steve Geis, Group Vice
7 President of Clinical Research was reported to have said the following: "Post-surgical pain can be
8 under-managed and cause patients tremendous discomfort. ... This investigational study suggests
9 that Bextra may offer promise in acute pain management and further study is required."²

10 60. Defendants widely and successfully marketed Bextra throughout the
11 United States by, among other things, conducting promotional campaigns that misrepresented the
12 efficacy of Bextra in order to induce a widespread use and consumption. Bextra was represented
13 to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made
14 misrepresentations by means of media advertisements, and statements contained in sales literature
15 provided to Plaintiff's prescribing physicians.

16 61. Despite knowledge of the dangers presented by Bextra, Defendants and
17 Defendants' predecessors in interest, through their officers, directors and managing agents for the
18 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy
19 the known defects of Defendants' product, Bextra, and failed to warn the public, including
20 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,
21 Bextra. Defendants and their officers, agents and managers intentionally proceeded with the
22 inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product,
23 Bextra, knowing that persons would be exposed to serious potential danger, in order to advance
24 their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a
25 conscious disregard for the safety of the public and particularly of Plaintiff.

26 62. In an elaborate and sophisticated manner, Defendants aggressively
27 marketed Bextra directly to consumers and medical professionals (including physicians and
28

² Press Release: docguide.com March 25, 2002.

1 leading medical scholars) in order to leverage pressure on third party payors, medical care
2 organizations, and large institutional buyers (e.g., hospitals) to include Bextra on their
3 formularies. Faced with the increased demand for the drug by consumers and health care
4 professionals that resulted from Defendants' successful advertising and marketing blitz, third
5 party payors were compelled to add Bextra to their formularies. Defendants' marketing campaign
6 specifically targeted third party payors, physicians, and consumers, and was designed to convince
7 them of both the therapeutic and economic value of Bextra.

8 63. Defendants represented that Bextra was similar to ibuprofen and naproxen
9 but was superior because it lacked any of the common gastrointestinal adverse side effects
10 associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance,
11 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with
12 long-term use. Defendants promoted Bextra as a safe and effective alternative that would not
13 have the same deleterious and painful impact on the gut, but that would be just as effective, if not
14 more so, for pain relief.

15 64. Bextra possessed dangerous and concealed or undisclosed side effects,
16 including the increased risk of serious cardiovascular events, such as heart attacks, unstable
17 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as
18 strokes. In addition, Bextra was no more effective than traditional and less expensive NSAIDs
19 and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal
20 bleeding. Defendants chose not to warn about these risks and dangers.

21 65. Defendants knew of these risks before the U.S. Food and Drug
22 Administration (the "FDA") approved Bextra for sale on November 16, 2001, but Defendants
23 ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied
24 inefficacy in its promotion, advertising, marketing, and sale of Bextra. Defendants' omission,
25 suppression, and concealment of this important information enabled Bextra to be sold to, and
26 purchased, or paid for by, the Consumers at a grossly inflated price.

27 66. Consequently, Bextra captured a large market share of anti-inflammatory
28 drugs prescribed for and used by patients. In 2004 alone sales of Bextra exceeded \$1 billion,

1 despite the significantly higher cost of Bextra as compared to other pain relievers in the same
2 family of drugs.

3 67. Because Defendants engaged in a promotional and marketing campaign
4 that featured an advertising blitz directly targeted to consumers, that touted Bextra as a safer drug
5 than other drugs in its class, while uniformly failing to disclose the health risks of Bextra,
6 Defendants were able to justify pricing Bextra significantly higher than the cost of generic
7 aspirin. In reality, that price inflation was not justified. Had Defendants disclosed the truth about
8 Bextra, Defendants would not and could not have reaped the billions of dollars in Bextra sales
9 that were achieved as a direct result of the concealment, omission, suppression, and obfuscation
10 of the truth.

11 68. Instead of revealing the risks of Bextra, Defendants intentionally
12 downplayed the risks from Bextra in news releases when Bextra's safety was challenged for the
13 first time in the mainstream media. *See e.g.*, Nov. 10, 2004 Pfizer News Release ("Pfizer Inc.
14 said a New York Times article published today draws unsubstantiated conclusions about the
15 cardiovascular safety of its Cox-2 medicine Bextra . . ."). Defendants similarly had earlier
16 downplayed the risks in communicating to healthcare providers misleadingly stating that
17 "available clinical information for Bextra suggests there is no increased risk of cardiovascular
18 thromboembolic events in people treated for osteoarthritis (OA) and rheumatoid arthritis (RA)"
19 Oct. 15, 2004 *Pfizer News Release*. Defendants intentionally, deliberately, knowingly, and
20 actively concealed, omitted, suppressed, and obfuscated important and material information
21 regarding the risks, dangers, defects, and disadvantages of Bextra from Plaintiff, the public, the
22 medical community, and the regulators. This concealment and omission was deliberate, knowing,
23 active, and uniform, was intended to induce and maximize sales and purchases of Bextra, and
24 prevented Plaintiff from obtaining all the material information that would be important to their
25 decisions as reasonable persons to purchase, pay for, and/or use Bextra.

26 69. Defendants' systematic, active, knowing, deliberate, and uniform
27 concealment, omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or
28 use Bextra; and caused Plaintiff's losses and damages as asserted herein.

1 70. Had Defendants done adequate testing prior to approval and “market
2 launch,” Pharmacia’s scientific data would have revealed significant increases in stroke and
3 myocardial infarction amongst the intended population of Bextra consumers. Adequate testing
4 would have shown that Bextra possessed serious side effects. Defendants should have taken
5 appropriate measures to ensure that their defectively designed product would not be placed in the
6 stream of commerce and/or should have provided full and proper warnings accurately and fully
7 reflecting the scope and severity of symptoms of those side effects should have been made.

8 71. In fact, post-market approval data did reveal increased risks of clotting,
9 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants
10 in order for them to gain significant profits from continued Bextra sales.

11 72. Defendants’ failure to conduct adequate testing and/or additional testing
12 prior to “market launch” was based upon their desire to generate maximum financial gains for
13 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2
14 inhibitor market.

15 73. At the time Defendants manufactured, advertising, and distributed Bextra
16 to consumers, Defendants intentionally or recklessly ignored and/or withheld information
17 regarding the increased risks of hypertension, stroke and/or myocardial infarctions because
18 Defendants knew that if such increased risks were disclosed, consumers would not purchase
19 Bextra, but instead would purchase other cheaper and safer NSAID drugs.

20 74. At all times relevant herein, Defendants engaged in a marketing campaign
21 with the intent that consumers would perceive Bextra as a better drug than its competitors and,
22 therefore, purchase Bextra.

23 **CLAIMS FOR RELIEF**

24 **FIRST CLAIM FOR RELIEF:**
25 **Negligence**

26 75. Plaintiff incorporates by reference all of the paragraphs of this Complaint
27 as if fully set forth herein.
28

1 76. Defendants owed Plaintiff a duty to exercise reasonable care when
2 designing, manufacturing, marketing, advertising, distributing, and selling Bextra. This duty
3 included the duty not to introduce a pharmaceutical drug, such as Bextra, into the stream of
4 commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side
5 effects.

6 77. At all relevant times to this action, Defendants owed a duty to properly
7 warn Plaintiff and the Public of the risks, dangers and adverse side effects of their pharmaceutical
8 drug Bextra.

9 78. Defendants breached their duties by failing to exercise ordinary care in the
10 preparation, design, research, testing, development, manufacturing, inspection, labeling,
11 marketing, promotion, advertising and selling of Bextra, including:

12 a. failing to use due care in the preparation and development of Bextra
13 to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

14 b. failing to use due care in the design of Bextra to prevent the
15 aforementioned risk of injuries to individuals when the drugs were ingested;

16 c. failing to conduct adequate pre-clinical testing and research to
17 determine the safety of Bextra;

18 d. failing to conduct adequate post-marketing surveillance and
19 exposure studies to determine the safety of Bextra;

20 e. failing to completely, accurately and in a timely fashion, disclose
21 the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff,
22 consumers, the medical community, and the FDA;

23 f. failing to accompany Bextra with proper warnings regarding all
24 possible adverse side effects associated with the use of Bextra;

25 g. failing to use due care in the manufacture, inspection, and labeling
26 of Bextra to prevent the aforementioned risk of injuries to individuals who used Bextra;

27 h. failing to use due care in the promotion of Bextra to prevent the
28 aforementioned risk of injuries to individuals when the drugs were ingested;

1 i. failing to use due care in the sale and marketing of Bextra to
2 prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

3 j. failing to use due care in the selling of Bextra to prevent the
4 aforementioned risk of injuries to individuals when the drugs were ingested;

5 k. failing to provide adequate and accurate training and information to
6 the sales representatives who sold Bextra;

7 l. failing to provide adequate and accurate training and information to
8 healthcare providers for the appropriate use of Bextra; and

9 m. being otherwise reckless, careless and/or negligent.

10 79. Despite the fact that Defendants knew or should have known that Bextra
11 caused unreasonable and dangerous side effects which many users would be unable to remedy by
12 any means, Defendants continued to promote and market Bextra to consumers, including
13 Plaintiff, when safer and more effective methods of pain relief were available.

14 80. Defendants were, or should have been, had they exercised reasonable care,
15 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,
16 they continued to market their products by providing false and misleading information with
17 regard to the safety and efficacy of Bextra.

18 81. Defendants knew or should have known that consumers such as Plaintiff
19 would foreseeably suffer injury as a result of their failure to exercise ordinary care as described
20 above.

21 82. As a result of Defendants' actions, Plaintiff, and the Plaintiff's prescribing
22 physicians were unaware, and could not have reasonably known or have learned through
23 reasonable diligence, that the Plaintiff had been exposed to the risks identified in this complaint,
24 and that those risks were the direct and proximate result of Defendants' acts, omissions, and
25 misrepresentations.

26 83. Defendants were, or should have been had they exercised reasonable care,
27 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,
28

1 they continued to market their products by providing false and misleading information with
2 regard to the safety and efficacy of Bextra.

3 84. Defendants knew or should have known that consumers such as Plaintiff
4 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described
5 above.

6 85. As a direct and proximate consequence of Defendants' acts, omissions, and
7 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has
8 required and will require healthcare and services; has incurred and will continue to incur medical
9 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
10 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
11 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
12 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
13 direct medical losses and costs include care for hospitalization, physician care, monitoring,
14 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

15 86. Defendants' conduct was committed with knowing, conscious, wanton,
16 willful, and deliberate disregard for the value of human life and the rights and safety of
17 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
18 as to punish Defendants and deter them from similar conduct in the future.

19 87. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
20 compensatory damages, and exemplary and punitive damages together with interest, the costs of
21 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

22 **SECOND CLAIM FOR RELIEF:**
23 **Strict Liability – Defective Design and Failure to Warn**

24 88. Plaintiff incorporates by reference all previous paragraphs of this
25 Complaint as if fully set forth herein and further alleged as follows:

26 89. At all times relevant to this action, Defendants were suppliers of Bextra,
27 placing the drug into the stream of commerce. Bextra was expected to and did reach Plaintiff
28 without substantial change in the condition in which it was manufactured and sold.

1 90. Bextra was unsafe for normal or reasonably anticipated use.

2 91. Bextra was defective in design or formulation because when it left the
3 hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous
4 than an ordinary consumer would expect. Bextra was also defective and unreasonably dangerous
5 in that the foreseeable risk of injuries from Bextra exceeded the benefits associated with the
6 design and/or formulation of the product.

7 92. At all times material hereto, Bextra was sold, marketed, distributed,
8 supplied, manufactured and/or promoted by the Defendant, in a defective and unreasonably
9 dangerous condition at the time it was placed in the stream of commerce in ways which include,
10 but are not limited to, one or more of the following particulars.

11 93. When placed in the stream of commerce, the drug contained unreasonably
12 dangerous design defects and was not reasonably safe as intended to be used, subjecting
13 Plaintiff's Plaintiff to risks which exceeded the benefits of the drug:

14 a. When placed in the stream of commerce, it was defective in design
15 and formulation, making use of the drug more dangerous than an ordinary consumer would
16 expect and more dangerous than other similar drugs;

17 b. The drug was insufficiently tested;

18 c. The drug caused harmful side effects which outweighed any
19 potential utility;

20 d. The drug was not accompanied by adequate instructions and/or
21 warnings to fully apprise the consumers, including the Plaintiff, of the full nature or extent of the
22 risks and side effects associated with use, thereby rendering Defendants liable to the Plaintiff and
23 Plaintiff, individually and collectively, pursuant to the Restatement (Second) of Torts, § 402A, as
24 adopted by the North Carolina Courts.

25 94. The drug was defective and unreasonably dangerous when it left the
26 possession of the Defendants in that it contained warnings insufficient to alert consumers,
27 including the Plaintiff, to the dangerous risks and reactions associated with the drug, including,
28

1 but not limited to, increased risk of cardiovascular events, and other serious and life threatening
2 side affects.

3 95. The Plaintiff could not have discovered any defect in the drug through the
4 exercise of care.

5 96. Defendants, as manufacturers of a prescription drug, are held to the level of
6 knowledge of an expert in the field.

7 97. Bextra as manufactured and supplied by Defendants was also defective due
8 to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate
9 reporting regarding the results of the clinical trials, testing and study. Defendants failed to
10 perform adequate testing before exposing Plaintiff to the medication, testing which would have
11 shown that Bextra had the potential to cause serious side effects including the adverse
12 cardiovascular event that which affected Plaintiff.

13 98. Bextra as manufactured and supplied by Defendants was defective due to
14 inadequate post-marketing warnings or instructions because, after Defendants knew or should
15 have known of the risk of injuries from Bextra, they failed to provide adequate warnings to the
16 medical community and the consumers, to whom they were directly marketing and advertising
17 Bextra; and, further, it continued to affirmatively promote Bextra as safe and effective.

18 99. Bextra was manufactured, distributed, tested, sold, marketed, advertised
19 and promoted defectively by Defendants, and as a direct and proximate cause of Defendants'
20 defective design of Bextra, Plaintiff used Bextra rather than other safer and cheaper NSAIDs. As
21 a result, Plaintiff suffered the personal injuries described above.

22 100. Information given by Defendants to the medical community and to the
23 consumers concerning the safety and efficacy of Bextra, especially the information contained in
24 the advertising and promotional materials, did not accurately reflect the potential side effects of
25 Bextra.

26 101. Defendants had a continuing duty to warn the Plaintiff of the dangers
27 associated with the drug.
28

1 102. Had adequate warnings and instructions been provided, Plaintiff would not
2 have taken Bextra, and would not have been at risk of the harmful side effects described herein.

3 103. Defendants acted with conscious and deliberate disregard of the
4 foreseeable harm caused by Bextra.

5 104. Defendants were, or should have been had they exercised reasonable care,
6 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,
7 they continued to market their products by providing false and misleading information with
8 regard to the safety and efficacy of Bextra.

9 105. Defendants knew or should have known that consumers such as Plaintiff
10 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described
11 above.

12 106. As a direct and proximate consequence of Defendants' acts, omissions, and
13 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has
14 required and will require healthcare and services; has incurred and will continue to incur medical
15 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
16 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
17 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
18 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
19 direct medical losses and costs include care for hospitalization, physician care, monitoring,
20 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

21 107. Defendants' conduct was committed with knowing, conscious, wanton,
22 willful, and deliberate disregard for the value of human life and the rights and safety of
23 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
24 as to punish Defendants and deter them from similar conduct in the future.

25 108. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
26 compensatory damages, and exemplary and punitive damages together with interest, the costs of
27 suit and attorneys' fees and such other and further relief as this Court deems just and proper.
28

THIRD CLAIM FOR RELIEF:
Breach of Express Warranty

109. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

110. Defendants expressly represented to Plaintiff and other consumers and the medical community that Bextra was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, particularly any unwarned-of side effects, and that it was adequately tested.

111. These warranties came in the form of:

a. Defendants' public written and verbal assurances of the safety and efficacy of Bextra;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for Bextra, which failed to warn of the risk of injuries inherent to the ingestion of Bextra, especially to the long-term ingestion of Bextra;

c. Verbal and written assurances made by Defendants regarding Bextra and downplaying the risk of injuries associated with the drug;

d. False and misleading written information, supplied by Defendants, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing Bextra during the period of Plaintiff's ingestion of Bextra, and;

e. advertisements.

112. The documents referred to above were created by and at the direction of Defendants.

113. Defendants knew or had reason to know that Bextra did not conform to these express representations in that Bextra is neither as safe nor as effective as represented, and that Bextra produces serious adverse side effects.

114. Bextra did not and does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, including unwarned- of side effects, and causes severe and permanent injuries.

115. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

116. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of Bextra.

117. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

118. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has required and will require healthcare and services; has incurred and will continue to incur medical and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the future; has suffered and will continue to suffer mental anguish, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

119. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

120. WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FOURTH CLAIM FOR RELIEF:
Breach of Implied Warranty

121. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

122. Defendants manufactured, distributed, advertised, promoted, and sold Bextra.

123. At all relevant times, Defendants knew of the use for which Bextra was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

124. Defendants were aware that consumers, including Plaintiff, would use Bextra for treatment of pain and inflammation and for other purposes.

125. Plaintiff and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to prescribe Bextra only if it was indeed of merchantable quality and safe and fit for its intended use. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for Bextra.

126. Bextra reached consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

127. Defendants breached their implied warranty to consumers, including Plaintiff; Bextra was not of merchantable quality or safe and fit for its intended use.

128. Defendants were, or should have been had they exercised reasonable care, in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless, they continued to market their products by providing false and misleading information with regard to the safety and efficacy of Bextra.

129. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described above.

130. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has

1 required and will require healthcare and services; has incurred and will continue to incur medical
2 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
3 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
4 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
5 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
6 direct medical losses and costs include care for hospitalization, physician care, monitoring,
7 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

8 131. Defendants' conduct was committed with knowing, conscious, wanton,
9 willful, and deliberate disregard for the value of human life and the rights and safety of
10 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
11 as to punish Defendants and deter them from similar conduct in the future.

12 132. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
13 compensatory damages, and exemplary and punitive damages together with interest, the costs of
14 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

15 **FIFTH CLAIM FOR RELIEF:**
16 **Fraudulent Misrepresentation & Concealment**

17 133. Plaintiff incorporates by reference all of the paragraphs of this Complaint
18 as if fully set forth herein.

19 134. Defendants' superior knowledge and expertise, their relationship of trust
20 and confidence with doctors and the public, their specific knowledge regarding the risks and
21 dangers of Bextra, and their intentional dissemination of promotional and marketing information
22 about Bextra for the purpose of maximizing its sales, each gave rise to the affirmative duty to
23 meaningfully disclose and provide all material information about Bextra's risks and harms to
24 doctors and consumers.

25 135. Defendants made fraudulent affirmative misrepresentations with respect to
26 Bextra in the following particulars:

27 a. Defendants represented through their labeling, advertising,
28 marketing materials, detail persons, seminar presentations, publications, notice letters, and

1 regulatory submissions that Bextra had been tested and found to be safe and effective for the
2 treatment of pain and inflammation; and

3 b. Defendants represented that Bextra was safer than other alternative
4 medications.

5 136. Defendants made affirmative misrepresentations; and fraudulently,
6 intentionally and/or recklessly concealed material adverse information regarding the safety and
7 effectiveness of Bextra.

8 137. Defendants made these misrepresentations and actively concealed adverse
9 information at a time when Defendants knew or had reason to know that Bextra had defects and
10 was unreasonably dangerous and was not what Defendants had represented to the medical
11 community, the FDA and the consuming public, including Plaintiff.

12 138. Defendants omitted, suppressed and/or concealed material facts concerning
13 the dangers and risk of injuries associated with the use of Bextra including, but not limited to, the
14 cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'
15 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the
16 serious nature of the risks associated with the use of Bextra in order to increase its sales.

17 139. The representations and concealment were undertaken by Defendants with
18 an intent that doctors and patients, including Plaintiff, rely upon them.

19 140. Defendants' representations and concealments were undertaken with the
20 intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to
21 induce and encourage the sale of Bextra.

22 141. Defendants' fraudulent representations evinced their callous, reckless,
23 willful, and depraved indifference to the health, safety, and welfare of consumers, including
24 Plaintiff.

25 142. Plaintiff's physician and Plaintiff relied on and were induced by
26 Defendants' misrepresentations, omissions, and/or active concealment of the dangers of Bextra in
27 selecting Bextra treatment.
28

1 143. Plaintiff and the treating medical community did not know that the
2 representations were false and were justified in relying upon Defendants' representations.

3 144. Had Plaintiff been aware of the increased risk of side effects associated
4 with Bextra and the relative efficacy of Bextra compared with other readily available
5 medications, Plaintiff would not have taken Bextra.

6 145. Defendants were, or should have been had they exercised reasonable care,
7 in possession of evidence demonstrating that Bextra caused serious side effects. Nevertheless,
8 they continued to market their products by providing false and misleading information with
9 regard to the safety and efficacy of Bextra.

10 146. Defendants knew or should have known that consumers such as Plaintiff
11 would foreseeably suffer injuries as a result of their failure to exercise ordinary care as described
12 above.

13 147. As a direct and proximate consequence of Defendants' acts, omissions, and
14 misrepresentations described herein, the Plaintiff, sustained serious cardiovascular injuries; has
15 required and will require healthcare and services; has incurred and will continue to incur medical
16 and related expenses; has suffered loss of wages and a diminished capacity to earn wages in the
17 future; has suffered and will continue to suffer mental anguish, diminished capacity for the
18 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
19 preexisting conditions and activation of latent conditions, and other such damages. Plaintiff's
20 direct medical losses and costs include care for hospitalization, physician care, monitoring,
21 treatment, medications, and supplies. Plaintiff will continue to incur such losses in the future.

22 148. Defendants' conduct was committed with knowing, conscious, wanton,
23 willful, and deliberate disregard for the value of human life and the rights and safety of
24 consumers, including Plaintiff, thereby entitling Plaintiff to punitive and exemplary damages so
25 as to punish Defendants and deter them from similar conduct in the future.

26 149. WHEREFORE, Plaintiff demands judgment against Defendants and seeks
27 compensatory damages, and exemplary and punitive damages together with interest, the costs of
28 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF
(Unjust Enrichment)

150. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein.

151. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of Bextra.

152. Plaintiff paid for Bextra for the purpose of managing pain safely and effectively.

153. Defendants have accepted payment from Plaintiff for the purchase of Bextra.

154. Plaintiff did not receive the safe and effective pharmaceutical product for which Plaintiff paid.

155. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendant represented Bextra to be.

156. WHEREFORE, Plaintiff demands judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:


1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;
4. Restitution;
5. Punitive and exemplary damages;
6. Pre-judgment and post-judgment interest as provided by law;
7. Recovery of Plaintiff's costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and

1 8. Such other and further relief as the Court deems just and proper.

2
3 Dated: September 13, 2007

Respectfully submitted,

4
5 By: _____



6 B. Kristian W. Rasmussen, III, FL Bar No. 0229430
7 LEVIN, PAPANTONIO, THOMAS,
8 MITCHELL, ECHSNER & PROCTOR, P.A.
9 316 South Baylen Street, Suite 600 (32502)
10 P. O. Box 12308
11 Pensacola, Florida 32591
12 Telephone: (850) 435-7023
13 Facsimile: (850) 435-7020

14 Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: September 13, 2007

Respectfully submitted,

By: 

B. Kristian W. Rasmussen, III, FL Bar No. 0229430
LEVIN, PAPANTONIO, THOMAS,
MITCHELL, ECHSNER & PROCTOR, P.A.
316 South Baylen Street, Suite 600 (32502)
P. O. Box 12308
Pensacola, Florida 32591
Telephone: (850) 435-7023
Facsimile: (850) 435-7020

Attorneys for Plaintiff